European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

DARONRIX

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Daronrix?

Daronrix is a vaccine. It is a suspension for injection that contains influenza (flu) viruses that have been inactivated (killed). It contains a flu strain called A/Viet Nam/1194/2004 (H5N1).

What is Daronrix used for?

Daronrix is a vaccine that can only be used once a flu 'pandemic' has been officially declared by the World Health Organization (WHO) or European Union (EU). A flu pandemic occurs when a new type (strain) of flu virus emerges that can spread easily from person to person because people have no immunity (protection) against it. A pandemic can affect most countries and regions around the world. Daronrix would be given according to official recommendations.
The vaccine can only be obtained with a prescription.

How is Daronrix used?

Daronrix is given in two doses, at least three weeks apart. It is given by injection into the upper arm muscle.

How does Daronrix work?

Daronrix is a 'mock-up' vaccine. This is a special type of vaccine that can be developed to help with the management of a pandemic.
Before a pandemic starts, nobody knows which strain of flu virus will be involved, so companies cannot prepare the correct vaccine in advance. Instead, they can prepare a vaccine that contains a strain of flu virus specifically chosen because nobody has been exposed to it, and to which nobody is immune. They can test this vaccine to see how people react to it, allowing them to predict how people will react when the flu strain causing a pandemic is included.
Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Daronrix contains small amounts of a virus called H5N1. The virus is whole, but it has been inactivated (killed) so that it does not cause disease. If a pandemic starts, the virus strain in Daronrix will be replaced by the strain causing the pandemic before the vaccine can be used.
When a person is given the vaccine, the immune system recognises the inactivated virus as 'foreign' and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus again. This helps to protect against the disease.
The vaccine also contains an 'adjuvant' (a compound containing aluminium) to stimulate a better response.

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How has Daronrix been studied?
The effects of Daronrix were first tested in experimental models before being studied in humans.
The main study of Daronrix included 387 healthy adults and compared the ability of different doses of Daronrix, with or without the adjuvant, to trigger the production of antibodies (immunogenicity). The participants received two injections of Daronrix, containing one of four different amounts of haemagglutinin (a protein found in flu viruses), with or without the adjuvant, 21 days apart. The main measures of effectiveness were the levels of antibodies against the flu virus in the patients' blood before vaccination, on the day of the second injection (day 21), and 21 days later (day 42).

What benefit has Daronrix shown during the studies?
According to criteria laid down by the Committee for Medicinal Products for Human Use (CHMP), a mock-up vaccine needs to bring about protective levels of antibodies in at least 70% of people for it to be considered suitable.
The study showed that Daronrix containing 15 micrograms of haemagglutinin and the adjuvant produced an antibody response that satisfies these criteria. 21 days after the second injection, 70.8% of the people receiving the vaccine had levels of antibodies that would protect them against H5N1.

What is the risk associated with Daronrix?
The most common side effects with Daronrix (seen in more than 1 in 10 people) are headache, pain and redness at the site of the injection, and fatigue (tiredness). These usually disappear within one to two days without treatment. For the full list of all side effects reported with Daronrix, see the Package Leaflet.
Daronrix should not be given to patients who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any substances found at trace levels in the vaccine, such as eggs, chicken protein or gentamicin sulphate (an antibiotic). If a pandemic has started, however, it may be appropriate to give the vaccine to these patients, as long as facilities for resuscitation are available.

Why has Daronrix been approved?
The CHMP concluded that Daronrix's benefits outweighed its risks, and that it had shown its suitability as a mock-up vaccine in preparation for a pandemic flu outbreak. The committee recommended that Daronrix be given marketing authorisation.
Daronrix has been authorised under "Exceptional Circumstances". This means that because the strain of flu virus that may cause a pandemic is not known, it has not been possible to obtain full information about the future pandemic vaccine. Every year, the European Medicines Agency (EMEA) will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Daronrix?
If a pandemic is declared, and if the company that makes Daronrix decides to market the vaccine, they will include the flu strain responsible in the vaccine. They will then collect information on the safety and effectiveness of the final pandemic vaccine, and submit this to the CHMP for evaluation.

Which measures are being taken to ensure the safe use of Daronrix?
If Daronrix is used during a pandemic, the company that makes it will collect information on the safety of the vaccine while it is being used. This will include information on its side effects and its safety in children, pregnant women, patients with severe conditions, and people who have problems with their immune systems.

Other information about Daronrix:
The European Commission granted a marketing authorisation valid throughout the EU for Daronrix to GlaxoSmithKline Biologicals s.a. on 21 March 2007.

The full EPAR for Daronrix can be found here.

This summary was last updated in 03-2007.